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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/989,261

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Eamonn P. Hobbs

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04/09/2007

REED SMITH, LLP

ATTN: PATENT RECORDS DEPARTMENT

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NEW YORK, NY 10022-7650

EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/989,261

Applicant(s)

HOBBS ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34, 43, 46-51, 54, 57-60, 64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46, 48, 50, 58, 60 and 65 is/are rejected.
- 7) ☒ Claim(s) 43, 47, 49, 51, 54, 57, 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 65, 48-51, 58 and 59 are objected to because of the following informalities: the phrase "in a patient" should be changed to "in the patient" as the phrase "a patient" has already been recited in claim 65 at line 18. Also, in claim 65, the period at the end of line 12 should be changed to a comma. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The wording in these two claims makes what Applicant is attempting to claim rather unclear. It would appear that Applicant is trying to claim that the zone is located on a portion of the catheter that is located within the patient when the catheter is implanted within the patient. If this is a correct assumption, the claims as currently worded would need to be changed to better reflect this.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 65, 43, 58 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Callol et al. (US Patent No. 6,749,628). Callol discloses a catheter assembly (Fig. 59) comprising: at least one tube (532) and a longitudinal companion member (533) coupled to one another at surfaces thereof along a predetermined zone (col. 41, lines 14-21 disclose that the two members are coupled together and that they are coupled in a zone which is exemplified by the members being only coupled at the tips), and a linear engagement member (536 is a joining wire, not a guidewire, that is used only to couple the two members together, and is not used in passing catheters over it to deliver the catheters to a site in the body, as described in col. 41, lines 21-27) extending longitudinally through said tube and said companion member engaging said tube and said companion member at said zone, said tube and said companion member held together solely at said zone (Fig. 59, col. 41, lines 14-21 disclose that they are held together only at the tip zone), said tube and said companion member each have a sidewall and said linear engagement member extends longitudinally within the sidewall of both of said tube and companion member (the linear engagement member/joining wire 536 extends within and through the sidewalls of the two members, just as the applicant's invention has the linear engagement member extending longitudinally within a carved out hollow space that the linear engagement member can slide into and out of

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when being inserted or removed from the assembly), each of the distal most and proximal most ends of the said linear engagement member being embedded in one of said sidewalls (as Fig. 59 discloses that the distal most end of the linear engagement member/joining wire 536 is embedded in the tube's sidewall (532) and col. 41, lines 23-27 disclose that the joining wire extends through the proximal end of 533 to the hub where it is locked in place to the wall of the hub further described in col. 28, lines 12-28), said tube, said companion member and said linear engagement member extending proximal of said zone by an amount sufficient to extend out of the body of a patient in whom the catheter is embedded (col. 41, lines 23-25 disclose that the joining wire/linear engagement member extends proximally out to the hub of the catheter which therefore means that it extends out the body of the patient, as the hub of a catheter is not placed within the patient as this is what is grasped and held in place during procedures), withdrawal of said linear engagement member causing said tube and said companion member to disconnect and permitting separate, independent withdrawal of said tube and said companion member from the patient (col. 41, lines 37-40).

In reference to claim 43, Callol discloses that the surfaces at the zone are flat surfaces (Fig. 59 discloses that the surfaces are flat between 532 and 533).

In reference to claim 58, Callol discloses that the zone is located on a portion of the catheter which is within the patient when the catheter is implanted in the patient (Fig. 59).

In reference to claim 60, Callol discloses that the linear engagement member is a surgical suture (Fig. 59).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (US Patent No. 6,749,628). Callol discloses the device substantially as claimed including a linear engagement member (Fig. 59, 536) extending proximally to a position outside the patient when the catheter is implanted in the patient (col. 41, lines 23-25 disclose the linear engagement member extends proximally to the hub which is located outside of the patient), said wire having a proximal end (col. 41, lines 23-25), said wire being withdrawn by accessing and pulling on said proximal end (col. 41, lines 37-40). Callol, however, does not disclose that the linear member is a set of two wires. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Callol by adding another linear engagement member such that there

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would be two wires for further support of the engagement and since it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Allowable Subject Matter

Claim 64 is allowed. The subject matter of claim 64 that has not been found within the prior art is the catheter assembly in combination with a flexible separating prong.

Claims 43, 47, 49, 51, 54 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 59 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 65, 43, 46-51, 54 and 57-60 have been considered but are moot in view of the new ground(s) of rejection.

With regards to Applicant's arguments that Callol discloses using a guidewire to couple the two members together, as described above, Fig. 59 discloses using a joining wire as a linear engagement member which is separate in function from the guidewire (537) used within that disclosed embodiment. The joining wire in Fig. 59 is used only

for joining the two members together and is not used as a track for sliding the catheters over it for placement of the catheters or other devices within the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons